REMARKS

Claims 1-20, 37-42, and 52-53 are currently pending in the application, of which claims 12 and 13, have been withdrawn from consideration. Claims 21-36 and 43-51 remain cancelled. Claims 1, 37, 52, and 53 have been amended to more clearly delineate the instant invention. Support for the amendments to the claims can be found in the specification. No new matter has been added by the amendments to the claims.

Amendment of any claim herein is not to be construed as acquiescence to any of the rejections/objections set forth in the instant Office Action, and was done to expedite prosecution of the application. Applicants make these amendments without prejudice to pursuing the original subject matter of this application in a later filed application claiming benefit of the instant application, including without prejudice to any determination of equivalents of the claimed subject mattered.

As an initial matter, Applicants wish to thank the Examiner for the courtesy of a telephonic interview ("the Interview") with the undersigned representatives on May 31, 2006. During the Interview, the reference US 6,211,273 (Bru-Magniez et al.) was discussed. US 6,211,273 describes microspheres having a diameter of less than 0.5 μm. Applicants' representatives urged that the '273 patent does not teach or suggest the claimed invention. In particular, Applicants' representatives urged that the '273 patent does not teach the claimed compositions, in which the mean particle size of the microparticle is between about 1.0 μm and 100 μm. Applicants' representatives additionally contended that the Declaration submitted by Applicants on May 31, 2005 demonstrated that microparticles of 2 μm in diameter are retained in the bladder for up to 48 hours, providing the unexpected result of slow release of an encapsulated agent. Although no final agreement was reached, the Examiner agreed to consider a Response in which Applicants' position was explained in detail.

Rejections under 35 U.S.C. §103(a)

Claims 1-11, 14-20, 37-42, 52, and 53 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bru-Magniez et al. (US 6,211,273). The Examiner asserts that the 37 C.F.R. §132 declaration (the "Declaration") submitted by Applicants on May 31, 2005 does not provide for microparticles meeting the instant claim 1 definition, and that no correlation exists between retention of a polymer and release of drug.

Applicants disagree and respectfully traverse. However, solely to expedite prosecution of the application, claims 1, 37, 52, and 53 have been amended to recite a microparticle having a mean particle size of between about 2.0 μm and about 100 μm.

Support for the amendment can be found at least in Examples 6 and 7 of the application as filed. Example 6 describes a microparticle formulation of an encapsulated agent, wherein the microparticle is about 2 μm in diameter. Example 7 describes the slow-release of a therapeutic agent encapsulated by a microparticle of about 2 μm in diameter in an animal with carcinoma in situ (CIS). Specifically, Table 1, at page 23 of the application as filed, provides data indicating that the therapeutic agent encapsulated in the microsphere treats cancer over a 1 week period. When the therapeutic agent is administered in its free form, 71% of the animals have CIS. This data suggests that the free therapeutic agent is not more than 29% effective, while the encapsulated therapeutic agent is effective in treating CIS.

Additionally, experiments 5.1 and 5.2 of the Declaration clearly demonstrate that the microparticles of the instant invention are retained in the bladder for up to 48 hours. Example 7 of the application as filed shows that the therapeutic agent is slowly released into the bladder, as indicated by the lack of CIS after 1 week, when compared to the direct administration of the free therapeutic agent. Applicants contend that microparticles of the instant application provide for the unexpected result of the controlled release of a drug, as the microparticles are retained and therefore provide a way of slowly releasing the therapeutic agent. For at least the reasons stated above, Applicants submit that the claims of the invention are not taught or suggested by US 6,211,273. Withdrawal of the rejection is respectfully requested.

In view of the above remarks, Applicants believe the pending application is in condition for allowance. Should any of the claims not be found to be allowable, the Examiner is requested to telephone Applicants' undersigned representative at the number below. Applicants thank the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 71699-55322.

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Respectfully submitted,

By _____

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